

## § 73.3111

Blue 36) (CAS Reg. No. 68187-11-1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of § 73.1015 (a) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[53 FR 41325, Oct. 21, 1988]

## § 73.3111 Chromium oxide greens.

(a) *Identity and specifications.* The color additive chromium oxide greens (chromic oxide) (CAS Reg. No. 1308-38-9), Colour Index No. 77288, shall conform in identity and specifications to the requirements of § 73.1327 (a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification

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requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986]

## § 73.3112 C.I. Vat Orange 1.

(a) *Identity.* The color additive is C.I. Vat Orange 1, Colour Index No. 59105.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used. A person intending to introduce a device containing C.I. Vat Orange 1 into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[50 FR 20407, May 16, 1985]

## § 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol.

(a) *Identity.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol is formed in situ in soft (hydrophilic) contact lenses.

(b) *Uses and restrictions.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol may be safely used to mark soft (hydrophilic) contact lenses with the

letter R or the letter L for identification purposes subject to the following restrictions:

(1) The quantity of the color additive does not exceed  $1.1 \times 10^{-7}$  grams in a soft (hydrophilic) contact lens.

(2) When used as specified in the labeling, there is no measurable migration of the color additive from the contact lens to the surrounding ocular tissue.

(3) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 22706, May 20, 1983]

**§ 73.3117 16,23-Dihydrodinaphtho[2,3-a:2',3'-i] naphth [2',3':6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.**

(a) *Identity.* The color additive is 16,23-dihydrodinaphtho [2,3-a:2',3'-i] naphth [2',3':6,7] indolo [2,3-c] carbazole-5,10, 15,17,22,24-hexone (CAS Reg. No. 2475-33-4), Colour Index No. 70800.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification

requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

**§ 73.3118 N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.**

(a) *Identity.* The color additive is N,N'-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide (CAS Reg. No. 82-18-8), Colour Index No. 61725.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

**§ 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.**

(a) *Identity.* The color additive is 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (CAS Reg. No. 130-20-1), Colour Index No. 69825.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.